UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

D-4 DR. DAVID LEWIS, et al.,

Defendants.
_____/

CRIMINAL NO. 18-CR-20800

HON. STEPHEN J. MURPHY III

UNITED STATES' RESPONSE TO DEFENDANTS' MOTION TO DISMISS CERTAIN COUNTS IN THE INDICTMENT (ECF No. 312)

The Court should deny Defendant Dr. David Lewis's Motion to Dismiss (ECF No. 312)—which Drs. Bothra, Edu, and Russo have joined (ECF Nos. 314, 315, & 321)—for three reasons. First, the motion is untimely because the deadline to file pretrial motions passed more than twenty months ago.

Second, even if the Court were to address the merits of defendants' motion, the Sixth Circuit has already held that the government need not allege "outside the usual course of professional practice" or "no legitimate medical purpose" when charging a doctor with a violation of § 841(a)(1).

Third, there is no legal support for the defendants' interpretation of the regulation, and it would result in an extreme result. Title 21, Section 1306.04(a) of the Code of Federal Regulations states that "A prescription for a controlled

substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Defendants propose interpreting this sentence in a manner that would effectively shield all pain doctors from prosecution under 21 U.S.C. § 841(a). That is, even if doctors prescribed opioids well in excess of the industry standard—in doses that could kill patients—defendant doctors would be immunized from prosecution as long as the patients had "some pain." The Court should deny this motion because defendants' proposed interpretation, and the extreme result that would follow, is contrary to the plain text of the regulation and controlling law.

The grounds for this response are set forth in the attached brief.

Respectfully submitted,

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Dated: January 7, 2022

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CRIMINAL NO. 18-CR-20800

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BRIEF IN SUPPORT OF UNITED STATES' RESPONSE TO DEFENDANTS' MOTION TO DISMISS CERTAIN COUNTS IN THE INDICTMENT (ECF No. 312)

Issues Presented

1. Whether the Court should deny defendants' motion to dismiss Counts 43–46 and 51–54 of the indictment[1] because it is untimely.

2. Whether the Court should deny defendants' motion because the Sixth Circuit has already held that when charging doctors, the government need not mention the good faith defense to § 841(a) violations.

3. Whether the Court should deny defendants' motion because the plain text of 21 C.F.R. § 1306.04(a), as well as controlling law, counsels against defendants' interpretation.

[1] Dr. Lewis filed a motion to dismiss Counts 43 and 53, (ECF No. 312), and Drs. Bothra, Russo, and Edu filed notices of joinder, adding Counts 44–46, 51, 52, and 54. (*See* ECF Nos. 314, 315, & 321).

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I. INTRODUCTION

Over forty-five years ago, the Supreme Court held that doctors could be prosecuted under 21 U.S.C. § 841 for illegally dispensing controlled substances. *United States v. Moore*, 423 U.S. 122, 138 (1975). Nonetheless, defendants now seek to interpret 21 C.F.R. 1306.04(a) in a manner that would allow doctors to prescribe opioids—dangerous narcotics that have killed tens of thousands and addicted many more[2]—in as high of doses and dosages as they would like, as long as their patients have some pain.

At the outset, the Court should deny defendant's motion because it is untimely. Under Federal Rule of Criminal Procedure 12 and the Court's scheduling orders in this case, the deadline to file a motion to dismiss based on a defect in the indictment has long passed, and no good cause justifies defendants' delay.

Second, pleading standards are different from burdens of proof at trial. The Sixth Circuit held decades ago that when charging doctors with violations of § 841(a)(1), the government need not mention "outside the usual course of practice" or "no legitimate medical purpose" in the indictment. *See United States v. Seelig*, 622 F.2d 207, 211–12 (6th Cir. 1980).

Third, even if the Court addresses the defendants' proposed interpretation of

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[2] *See* https://www.cdc.gov/drugoverdose/deaths/prescription/maps.html (In 2019 alone, more than 14,000 deaths occurred from overdoses involving prescription opioids).

the regulation, it should still deny the motion because there is no authority that supports defendants' reading of the regulation.

II. BACKGROUND

In a fifty-six-count indictment, a grand jury charged Drs. Bothra, Edu, Lewis, and Russo—as well as two other doctors—with health care fraud, conspiring to commit health care fraud, unlawful distribution of controlled substances, and conspiring to unlawfully distribute controlled substances in violation of 18 U.S.C. §§ 1347, 1349, & 2 and 21 U.S.C. §§ 841(a)(1) & 846. (Indictment, ECF No. 1, PageID.1–33). Counts 43–46 and 51–54—the only counts that the defendants challenge—allege a conspiracy to unlawfully distribute controlled substances, as well as substantive drug counts, because the "prescription opioids were distributed outside the usual course of professional medical practice." (*Id.* at PageID.27–28, 30–32).

This case differs from the typical pill mill case, as the defendants did not just recklessly prescribe large dosages of opioids. Rather, they wrote prescriptions for narcotics only if their patients submitted to unnecessary medical treatments, such as facet injections (spinal injections), urine analyses that were not relied upon for decision-making purposes, durable medical equipment such as back braces, and sham physical therapy. (*Id.* at PageID.9–23). In total, the defendants submitted claims for more than $182.5 million to Medicare, $272.6 million to Medicaid, and

$9.2 million to Blue Cross/Blue Shield of Michigan. They are responsible for over 13,217,987 dosage units of Schedule II opioids being issued. (*Id.* at PageID.2).

III. ARGUMENT

A. Defendants' motion is untimely and should be denied on that basis alone

Rule 12(b)(3)(B) states that before trial, the defense must raise any issues concerning a defect in the indictment, such as a failure to state an offense, in a pretrial motion. Fed. R. Crim. P. 12(b)(3)(B)(v). Rule 12(c)(1) permits the Court to set deadlines for such motions. If a party misses that deadline, the motion is untimely, and the Court cannot consider the merits unless the moving party shows good cause for the delay. Fed. R. Crim. P. 12(c)(3); *see also United States v. Walden*, 625 F.3d 961, 964–65 (6th Cir. 2010) (affirming district court's denial of motion to suppress as untimely where no good cause was shown).[3]

In this case, the Court set initial scheduling orders for Drs. Bothra, Lewis, Edu, and Russo. (ECF Nos. 11, 12, 29, & 47). All four of those orders required the defendants to file pretrial motions within twenty days of the date of arraignment. (ECF No. 11, PageID.49; ECF No. 12, PageID.57; ECF No. 29, PageID.96; ECF No. 47, PageID.128).

[3] After *Walden* was decided, the good cause standard in section (e) was incorporated into section (c)(3). *See United States v. Soto*, 794 F.3d 635, 648 & n.3 (6th Cir. 2015).

Subsequently, in a series of stipulated orders, the Court ultimately adjourned the pretrial motion deadline to April 17, 2020. (*See* ECF No. 81; ECF No. 110; ECF No. 130, PageID.681). Aware of the April 17, 2020 deadline, Dr. Lewis filed a motion to suppress on April 16, 2020. (ECF No. 194, PageID.1363). Dr. Lewis then filed a motion to extend the April 17, 2020 pretrial motion deadline. (ECF No. 215, PageID.1447). In response to that motion, the Court said it "will not extend the deadline here"; rather, the Court would consider in a later motion, based on additional discovery, whether good cause exists to extend the deadline. (Order, ECF No. 227, PageID.1533–34). Notably, this instant motion alleges a defect in the indictment and is not based on any additional discovery.

Simply put, the pretrial motion deadline passed more than twenty months ago. Thus, under Rule 12(c)(3), defendants must show good cause as to why the motion should not be denied as untimely. This is problematic for the defense, because as the Court noted during the hearing on December 16, 2021, the basis for defendants' motion—21 C.F.R. § 1306.04(a)—has been in existence since the 1970s.

Moreover, counsel for Dr. Lewis, the lead defendant on this motion, has known about the underlying issue for some time. As he admits in another pleading, he briefed this issue in another case more than two years ago. (*See* ECF No. 318, PageID.2305 & n.4) (noting that *Naum v. United States* is another case "pending

before the Supreme Court dealing solely with the conjunctive or disjunctive issue" and that the "undersigned counsel is counsel for [Naum]"). The decision in the *Naum* district court, which rejected the same argument that the defendants present here, was issued back on October 2, 2019. *United States v. Naum*, No. 1:18CR1-2, 2019 WL 4862056, at *2 (N.D. W. Va. Oct. 2, 2019) ("[T]he Government may prove the third element of the offense by showing that Naum's actions either were (1) not for legitimate medical purposes or (2) beyond the bounds of medical practice. Every other circuit court to address this question has reached the same conclusion."). Accordingly, there seems to be no reason Dr. Lewis and his co-defendants could not have filed a similar pretrial motion in this case before April 17, 2020.

For these reasons, defendants' motion is untimely, and defendants cannot show good cause as to why the Court should consider the merits of the motion.

B. The indictment is properly pled

Nonetheless, even if the Court addresses the merits of defendants' motion, it should still deny it because the indictment is more than sufficient in light of controlling law.

An indictment is adequate if it apprises the defendant of the crime charged with sufficient particularity to enable him to prepare a proper defense and enable him to plead his acquittal or conviction as a bar to a later prosecution for the same

offense. *See United States v. Birmley*, 529 F.2d 103, 108 (6th Cir. 1976); *see also United States v. Anderson*, 182 F.3d 918 (Table), 1999 WL 503519, at *3 (6th Cir. 1999) ("[A]n indictment is presumed sufficient if it tracks the statutory language, cites the elements of the crimes charged, and provides approximate dates and times.") (citing *Hamling v. United States*, 418 U.S. 87, 117–18 (1974)).

As noted earlier, it was the Supreme Court's *Moore* decision that provided the basis for the government to bring violations of § 841(a)(1) against doctors. *See Moore*, 423 U.S. at 138. And it is § 841(b) that establishes criminal penalties for violations of § 841(a). The regulation itself, 21 C.F.R. § 1306.04(a), notes that penalties for controlled substance violations are contained within Title 21 of the United States Code.

Accordingly, over forty years ago, the Sixth Circuit held that when charging doctors with violating § 841(a)(1), an indictment need not mention the good faith defense from *Moore*: "the allegation of distribution in violation of § 841(a)(1) includes the legal definition that the drugs were not dispensed, i.e., distributed in the usual course of professional practice." *See United States v. Seelig*, 622 F.2d 207, 211 (6th Cir. 1980). "That counts 165–174 of the indictment do not state this allegation expressly does not render them defective." *Id.* at 211–12.

The Eleventh Circuit later agreed with *Seelig* and noted that other circuit courts had as well. *See United States v. Steele*, 147 F.3d 1316, 1319–20 (11th Cir.

1998). For example, the court observed that "[t]wenty years ago the Seventh Circuit said that an indictment charging a physician with dispensing controlled substances need not allege that the prescriptions he wrote were outside the course of his professional practice." *Id*. (citing *United States v. Roya*, 574 F.2d 386, 391 (7th Cir. 1978)). The court then remarked that the Sixth Circuit had issued the same ruling. *Id.* (citing *Seelig*). Finally, the Eleventh Circuit noted that the "same rule has been in effect in the Third Circuit for six years." *Id.* (citing *United States v. Polan*, 970 F.2d 1280, 1282 (3d Cir. 1992)).

In this case, the government pled that the defendants "knowingly, intentionally and unlawfully distribute[d] controlled substances in violation of 21 U.S.C. § 841(a)(1)." (Indictment, ECF No. 1, PageID.27–28, 30–32). According to *Seelig*, that was all the government needed to do. But the indictment went even further by alleging that the "prescription opioids were distributed outside the usual course of professional medical practice." (*Id.*). Therefore, the government adequately pled § 841(a)(1) charges against Drs. Lewis, Bothra, Russo, and Edu in Counts 43–46 and 51–54 of the indictment, and the Court should deny defendant's motion.

C. No authority supports defendants' interpretation of 21 C.F.R. § 1306.04(a)

1. The history of the regulation undermines defendants' position

Although it is indisputable that the government properly pled § 841(a)(1) violations against the defendants, because this fight may rear its head again when discussing jury instructions, it should be noted that defendants' interpretation of 21 C.F.R. § 1306.04(a) is not supported by any authority. The starting point is the regulation itself.

Congress passed the Comprehensive Drug Abuse Prevent and Control Act of 1970, after which DOJ issued a rule in the Federal Register, stating that a prescription for a controlled substance was "effective" only if it was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." (Ex. 1, 21 C.F.R. § 306.04(a)). The rule explicitly put the onus of "proper prescribing and dispensing" on the practitioner. *Id.* In 1973, DEA took over rulemaking authority for controlled substances under Title 21, and § 306.04(a) was redesignated as § 1306.04(a). 38 FR 26609. Section 1306.04(a) has not been amended since then.

On October 17, 2000, Congress passed the Drug Addiction Treatment Act of 2000. 70 FR 36339, 2005 WL 1464959. As part of the agency rulemaking process, DEA noted that during "the late 1960s and the early 1970s, … there were no clear

means for differentiating legitimate treatment efforts using [methadone] … from bogus clinics or unethical practitioners distributing methadone to addicts under the guise of treatment," resulting in wide-scale diversion. 68 FR 37430, 2003 WL 21438916. These comments indicated the government's continued focus on the prescribing habits of medical practitioners.

The current version of 21 C.F.R. § 1306.04(c) became final in 2005, and in comments, DEA reiterated that to "be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice (§ 1306.04(a))." 70 FR 36338-02, 2005 WL 1464959. Accordingly, the rulemaking process for § 1306.04(a)—and the other portions of § 1306.04—makes it clear that both prongs are necessary for a prescription to be legitimate; one alone is not sufficient. The logical converse is that a prescription is ***unlawful*** if it ***either*** lacks a legitimate medical purpose ***or*** is outside the course of professional practice.

2. Relevant statutes, Supreme Court law, and Sixth Circuit law contradict defendants' interpretation

For a schedule II-controlled substance like an opioid to be dispensed, there must be "a written prescription of a practitioner." 21 U.S.C. § 829(a). A "practitioner" means a medical provider who "distribute[s], dispense[s] or conduct[s] research with respect to … a controlled substance in the course of

professional practice or research." *Id.* at § 802(21). Those are the exceptions referenced in the beginning of § 841(a)(1): "***Except as authorized by this subchapter***, it shall be unlawful for any person knowingly or intentionally (1) to manufacture, distribute, or dispense … a controlled substance." (emphasis added). There is no mention of "legitimate medical purpose" in these statutes.

In 1975, the Supreme Court decided the seminal *Moore* case, holding that a medical provider may be prosecuted for illegally dispensing controlled substances under 21 U.S.C. § 841. 423 U.S. 122 at 138. In so holding, the Court noted its approval of the trial court's instruction that "a physician who knowingly or intentionally, did dispense or distribute methadone by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." *Id.* at 138–39. It further held that the "evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds 'of professional practice.'" *Id.* at 142. As examples of such improper conduct, the Court noted that the respondent "gave inadequate physical examinations or none at all," ignored the results of tests, and did not regulate the dosage of controlled substances that he distributed. *Id.*[4]

[4] The indictment in this case alleges similar conduct by Drs. Lewis, Bothra, Edu, and Russo. (ECF No. 1, PageID.9–10).

A few years after the *Moore* decision, the Sixth Circuit remarked that courts had interpreted the statutory phrase "not in the usual course of professional practice" to have "no difference in the meaning[]" from the regulatory phrase "legitimate medical purpose." *United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978) (citations omitted). It further commented that determining whether conduct was "outside the usual course of professional practice" was a highly factual one, usually reliant on testimony by expert witnesses as to the generally acceptable standards of medical practice for issuing specific prescriptions. *Id.* at 784–85.

In 1981, the Sixth Circuit further fleshed out the meaning of "usual course of professional practice," noting that good faith connotes an "observance of conduct" in conformity with what a physician "should reasonably believe to be proper medical practice." *United States v. Voorhies*, 663 F.2d 30, 33–34 (6th Cir. 1981). The court's choice of language—should reasonably believe—suggested that a doctor's subjective good faith, rather than objective good faith, was not a defense.

Multiple subsequent Sixth Circuit cases bolster the observation in *Kirk* that the statutory phrase is synonymous with the regulatory phrase. *See, e.g.*, *United States v. August*, 984 F.2d 705, 708, 712–13 (6th Cir. 1992) (focusing on the phrase "usual course of professional practice."); *United States v. Polito*, 111 F.3d 132 (Table), 1997 WL 178879, at *4 (6th Cir. 1997) (citing *Kirk* and emphasizing only the "usual course of medical practice"); *United States v. Sawaf*, 129 F. App'x

136, 142 (6th Cir. 2005) (emphasizing only the phrase "legitimate medical purpose."). Going even further in *United States v. Johnson*, the Sixth Circuit listed three elements for convicting a physician under § 841(a)(1), and it combined "legitimate medical purpose" and "outside the usual course of practice" as one element—the third element. 71 F.3d 539, 542 (6th Cir. 1995).

In 2006, the Supreme Court decided *Gonzales v. Oregon*, 546 U.S. 243 (2006). The defendants make much of this case, (ECF No. 312, PageID.2283–84), but it does not support their motion. The question was whether the Attorney General had the authority to declare in an interpretative rule that assisting suicide was not a legitimate medical purpose. 546 U.S. at 248, 253–54, 257. Aside from quoting the language of 21 C.F.R. § 1306.04(a), *see* 546 U.S. at 256, the opinion said nothing to suggest that "the usual course of medical practice" and "legitimate medical purpose" must be read in the conjunctive.

Indeed, the Sixth Circuit agreed that *Gonzales* does not support defendants' argument. In *United States v. Volkman*, the defendant, a doctor, sought to include a jury instruction based on *Gonzales* that said he could be found guilty only if he "used his prescription-writing power as a means to engage in the illicit drug-dealing and trafficking as conventionally understood." 797 F.3d 377, 385 (6th Cir. 2015). The Sixth Circuit, citing cases from the Eighth and Tenth Circuits about the lack of import of *Gonzales* on criminal prosecutions, held that "*Gonzales* did not

impose new requirements to prove a violation of the CSA." *Id.* at 386. The court went on to praise the district court's jury instructions, which repeatedly applied the two phrases as one element. *Id.* at 387–88 ("dispensed the drug for a legitimate medical purpose in the usual course of accepted medical practice," "acted with a legitimate medical purpose in the course of usual professional practice," and "acted without a legitimate medical purpose outside the course of usual professional practice."). Furthermore, the Sixth Circuit approvingly quoted language from the Eighth Circuit that "post-*Gonzales*, knowingly distributing prescriptions outside the course of professional conduct is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances." *Id.* at 386 (citation omitted). There is no mention of "legitimate medical purpose" in that unequivocal statement.

Finally, in 2019, the Sixth Circuit decided *United States v. Godofsky*, 943 F.3d 1101 (6th Cir. 2019). The court first noted that the term "good faith" does "not mean *subjective* good faith. Rather, this is more or less *objective* good faith…." *Id.* at 1025–26. Then addressing *Volkman*, the court reiterated its approval of jury instructions that list "usual course of professional practice" and "no legitimate purpose" as one phrase. *Id.* at 1026–27.

Taken as a lengthy whole, statutes, case law from the Supreme Court, and cases from the Sixth Circuit do not support defendants' argument. Rather, if the

two terms are not interchangeable, at the very least the government need only prove one—that a prescription was issued outside the usual course of professional practice—to sustain a conviction under § 841(a)(1).

3. Courts from this district, as well as other circuit courts, support the finding that 21 C.F.R. § 1306.04(a) is read in the disjunctive

A lack of support for defendants' argument carries over to district court cases within this district, as well as cases from other circuit courts. For example, Chief Judge Hood previously addressed defendants' argument in *United States v. Weekes*, No. 17-cr-20155, 2018 WL 3956487, at *3–4 (E.D. Mich. Aug. 17, 2018). The defendant argued that count II was deficient "because it does not state that he prescribed for 'other than a legitimate medical practice.'" *Id.* at *3. The court, citing *Volkman*, criticized the defendant's argument as "based on outdated case law." *Id.* at *4.

The court went on to say that "a logical reading of 21 C.F.R. § 1306.04 … shows that liability is not conjunctive." *Id.* Rather, "[b]oth prongs are necessary for a prescription to be legitimate; one is not sufficient. The logical converse is that a practitioner is unauthorized to dispense a controlled substance if the prescription *either* lacks a legitimate medical purpose or is outside the course of professional practice." *Id.* (quoting *United States v. Armstrong*, 550 F.3d 382, 397 (5th Cir.

2008), *overruled on other grounds by United States v. Balleza*, 613 F.3d 432, 433 (5th Cir. 2010)).

Chief Judge Hood's ruling in *Weekes* is in conformity with decisions from the Fourth, Fifth, Tenth, and Eleventh Circuits. *See, e.g.*, *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995) ("[T]he evidence must show that the defendant's "actions were not for legitimate medical purposes in the usual course of his professional medical practice ***or*** [were] beyond the bounds of medical practice." (emphasis added); *Armstrong*, 550 F.3d at 397 ("knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances"); *United States v. Nelson*, 383 F.3d 1227, 1232–33 (10th Cir. 2004) ("We conclude that … [a] practitioner has unlawfully distributed a controlled substance if she prescribes the substance ***either*** outside the usual course of medical practice ***or*** without a legitimate medical purpose) (emphasis added); *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008) (affirming instruction that government must prove not for legitimate medical purpose ***or*** beyond bounds of medicine).

Perhaps what is most telling about defendants' motion is that they ***do not cite a single case*** holding that the government must prove both "outside the usual course of professional practice" and "no legitimate medical purpose" in order to sustain a conviction under § 841(a)(1). (*See generally* ECF No. 312). The only

case they even suggest holds this way is *United States v. Simon*, 12 F. 4th 1 (1st Cir. 2021). (*See* ECF No. 312, PageID.2282). But a better reading of *Simon* is that, relying on *Moore* and *Volkman*, it found "no legitimate medical purpose" to be synonymous with "outside the usual course of professional practice." *See Simon*, 12 F. 4th at 24 (noting as part of string cites that in *Moore*, the government had to prove that the defendants had prescribed controlled substances outside the usual course of professional practice, and in *Volkman* for no legitimate purpose).

Even the *Naum* district court, where defense counsel previously raised this exact issue, found against defendants' interpretation. *United States v. Naum*, No. 1:18-cr-1-2, 2019 WL 4862056, at *2 (N.D. W. Va. Oct. 2, 2019) ("**The government was not required to prove that Naum's prescriptions were issued without a legitimate medical purpose**."). The Fourth Circuit likewise disagreed with defendants. *United States v. Naum*, 832 F. App'x 137, 142 (4th Cir. 2020) ("The Government is not required to prove both prongs….").

Simply put, the government is not aware of any authority that supports defendants' construction of 21 C.F.R. § 1306.04(a)—and apparently defendants are not aware of any such authority either.

IV. CONCLUSION

The Court should deny defendants' motion as untimely. Nevertheless, long-existing Sixth Circuit law establishes that the government adequately pled § 841(a)(1) violations against Drs. Lewis, Bothra, Edu, and Russo.

And as to the burden of proof at trial, case law from the Supreme Court and the Sixth Circuit is clear: to convict a physician under 21 U.S.C. § 841(a)(1), the government need only prove that his prescribing was outside the usual course of professional practice (whether issued for "some pain" or not).

For all of these reasons, the Court should deny defendants' motion and allow all counts of the indictment to proceed to trial.

Respectfully submitted,

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Dated: January 7, 2022

CERTIFICATE OF SERVICE

I hereby certify that on January 7, 2022, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system.

/s/Brandon C. Helms
Brandon C. Helms
Assistant United States Attorney